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10/528,802	03/23/2005	Greta Van Der Berghe	BERGHE1	6222

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EXAMINER	
HADDAD, MAHER M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,802	VAN DER BERGHE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-72* is/are pending in the application.

4a) Of the above claim(s) *53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51,52 and 54-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/07/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 51-72 are pending.

2. Applicant's election with traverse of Group II, claims 51-52 and 54-72, drawn to a method comprising a use of mannan-binding lectin (MBL), for the treatment/reducing of a patient suffering from *transplantation* filed on 5/18/07, is acknowledged.

Applicant's traversal is on the grounds that group II has a subcombination/combination relationship to group III, and hence, under PCT administrative instructions, Annex B, part 1, para. (c) (i), there is unity if the subcombination (group II) avoids the prior art (the Examiner has not made any comments re Thiel's teachings on transplantation) and the claimed combination includes all limitations of the subcombination (group III is so defined). This is not found persuasive because independent claim 51 does not avoid the prior art of Thiel's, in addition to the art under 102 and 103 below. Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention as set forth in the previous Office Action. Further, see the art under 102 and 103 below.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 53 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 51-52 and 54-72 are under examination as they read on a method comprising a use of mannan-binding lectin (MBL), for the treatment/reducing of a patient suffering from *transplantation.*

5. Applicant's IDS, filed 10/7/05, is acknowledged.

6. Claims 51, 61-62 are objected to for the following informalities:

A. Claim 51, uses the phrase "a use of mannan-binding lectin (MBL)". Given the non-statutory and not appropriate for US practice (see MPEP 2173.05(q)), it is recommended that the claim recite an active, positive steps delimiting how this use is actually practiced.

B. Claim 61 uses "and/or" in listing Markush species, the Office recommends the use of "and" when listing Markush species.

C. Claim 62, line 4, contains extra "or" after the term "comprising". Correction is required.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 56, 59-61, 64-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The phrase "for example" in claim 56 renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

B. Claim 61 is indefinite in reciting "preferably" because the narrow range within the broad range using the term "preferably" renders the claim indefinite.

C. The "MBL polypeptide monomer" recited in claims 59 has no antecedent basis in base claim 51. Base claim 51 only recites a MBL.

D. The "medicament" recited in claims 64-70 has no antecedent basis in base claim 51. Base claim 51 only recites a MBL.

E. The "said other treatment" recited in claim 70 has no antecedent basis in base claim 51. Base claim 51 only recites one treatment with MBL.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 51-52 and 54-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrases "and/or" claimed in claims 51 and "mammalian polypeptide monomer" in claim 59 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 1/25/06 does not point to the specification for support for the newly added limitations as claimed in claim 51 and 59. However, the specification does not provide a clear support for treating the claimed combination of diseases and the claimed mammalian polypeptide monomer. The specification discloses transplantation (see page 12, line 26; page 15, line 29 and page 28, line 21, in particular); however, the specification does not disclose any combination of diseases to be treated with MBL. The combination of treating multiple diseases

is not contemplated in the specification. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

11. Claims 51-52 and 54-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide **enablement** a method comprising a use of mannan-binding lectin (MBL) for the treatment of a patient in need of transplantation as claimed in claims 51-52 and 54-72. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The claims require the use of mannan-binding lectin (MBL) (claim 51) wherein the MBL polypeptide monomer is a mammalian polypeptide monomer (claim 59), wherein the mammalian MBL polypeptide monomer is a human polypeptide monomer (in claim 60). The specification fails to establish the structure of any mammalian MBL. "MBL" is an arbitrary protein name. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of MBL polypeptides (MBL A, MBL B, MBL C or MBL D) broadly encompassed by the claims. U.S. Patent 7,211,396 teaches that human MBL gene (mbl2) shows a number of allelic variants. Some occur in the promoter region, the two most significant occurring at positions -550 (H or L) and -221 (Y or X); a further variant occurs in the 5'-untranslated region at position +4 (P or Q); and three occur in exon 1, at position +223 (A or D, Arg52Cys), +230 (A or B, Gly54Asp) and +239 (A or C, Gly57Glu). The promoter haplotypes HY, LY and LX are associated with high, medium and low plasma levels of MBL, respectively, whereas the haplotypes of exon 1 affect the structure and association of the protein chains. Among A/A genotypes (i.e. with a normal collagenous region), only the LXP/LXP genotypes showed low plasma MBL levels. A/B, A/C and A/D genotypes (i.e. heterozygous for normal and abnormal collagenous regions) showed reduced plasma MBL levels as determined by the old method described; when this was combined with an LX haplotype, even lower levels were recorded. B/B, C/D and D/D genotypes (i.e. with an anomaly of all collagenous regions) showed very low levels of MBL as determined by the old method, even though none of these subjects showed an LX haplotype. The frequencies of the exon 1 haplotypes A, B, C and D in the

Danish donors were 0.76, 0.135, 0.020 and 0.085, respectively. This means that the frequencies of A/A, B/B, C/C and D/D genotypes will be the square of these, i.e. affecting 58.76%, 1.82%, 0.04% and 0.72% of the population, respectively.

At issue whether the specification is enabled for a method of treating any transplantation in a patient characterized by low blood level of MBL. The specification fail to provide guidance on which organ/cell can be transplanted using claimed method. The specification does not provide sufficient enablement for transplanting any organ or any tissue rejection using the claimed MBL. Toogood et al (Transplantion 62:851-855, 1996) teaches that the mechanisms of rejection in small bowel and other solid organ grafts are likely to be different (see abstract in particular). Importantly, Toogood et al concluded that there are significant immunological differences between the gut wall compartment of a small bowel transplant and other vascularized allografts (see page 855, 1st col., lines 13-16 in particular). Therefore, it is not clear that the skilled artisan could predict the efficacy of the "MBL" to treat any condition including any organ or tissue rejection. Further, the specification is not enabled for organ/cell related (allografts) or organ/cell unrelated (xenografts), which is expected to lead to more damage or/and destruction of the grafted organs, wherein the level of immune suppression and/or rejection is expected to be greater in xenograft recipients. Therefore, it is not clear that the skilled artisan could predict the efficacy of the MBL on any organ or tissue rejection. It is unclear which organ/tissue/cell transplantation would be candidates for in vivo treatment with MBL.

The present invention is based on the particular finding that low level MBL increase the risk of death of subjects due to infection observation only, applicant concludes that the scope of the MBL encompassed by the claimed invention can have biological activity to treat any transplantation and be provided as pharmaceutical compositions to subjects including human to effectively treat transplantation. The specification provides insufficient guidance to enable one skill in the art to use of MBL to transplantation to the extent that the MLB level in the patient is kept between 1000-2000 ng/ml. The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation. The specification lacks empirical data on using transplantation principles to design and test specific MBL in animal models with the prospect of ultimate relevance in human disease. The status of the art that the art is unaware of successful methods with chemically analogous agents that increase the level of blood MBL level for the use in transplantation, a more complete statement of how to use must be supplied.

In order for this therapy to be predictable, the MBL must play a role in transplantation. However, Hjelmesaeth et al (J Am Soc Nephrol 17:1746-1754, 2006) teach that serum levels of MBL was not significantly associated with patient survival, cardiovascular (CV) death, or graft loss (see abstract). Further, Hjelmesaeth et al teach that MBL was not associated with 8-yr survival or CV death. This finding is supported to some extent by Dahl et al (J. Exp. Med. 199:1391-1399, 2004) results of a large Danish population-based follow-up study (8-24 yr) of approximately 10,000 adults that showed that MBL deficiency is not a major risk factor for morbidity and death. Dahl et al found that no evidence for differences in infectious disease or mortality in MBL-deficient individuals versus controls. Dahl et al conclude that their result

suggest that MBL deficiency is not a major risk factor for infection, other serious common diseases, or death in the adult Caucasian population (see page 1397, last ¶). Further, support come from Berger et al (Am J Transplant 5: 1361-1366, 2005) who teach that higher MBL levels seem to be associated with a more severe form of rejection leading to treatment failure and graft loss (see abstract). Berger et al (J Am Soc Nephrol. 2007 Aug;18(8):2416-22) teach that Low pretransplantation mannose-binding lectin levels predict superior patient and graft survival after simultaneous pancreas-kidney transplantation (see title). Furthermore, US 2004/0259771 teaches and claims methods of treating transplantation using MBL inhibitors (see published claims 40 and 44).

Due to the contradictory and seemingly mutually exclusive activity of the MBL, undue experimentation would be required of the skilled artisan to determine the effect of MBL on any particular transplantation in view of the instant disclosure. Further, there is insufficient evidence or nexus that would lead the skilled artisan to predict the ability of MBL on any particular transplantation. Thus, faced with contradictory and seemingly mutually exclusive function regarding the activity of the claimed MBL, undue experimentation would be required of the skilled artisan to determine the effect of MBL on a particular transplantation. Further, absent a positive correlation between MBL and treatment of transplantation, for one of skill in the art to practice the invention as claimed would require a level of experimentation that is excessive and undue.

The lack of any working examples is exacerbated because the invention is in a highly unpredictable art-treating transplantation- and while the level of skill of in the art may be high, the state of the prior art is that it is in fact unknown and untested what are the underlying molecule and physiologic bases of the therapeutic effects of MBL protein in the treatment of transplantation.

The "another treatment" claimed in claims 68-70, however, the specification provides no single other treatment that can be used to treat transplantation. The skilled in the art would not know other treatment are encompassed in the claimed invention.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e1) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

13. Claims 51-52, 54-67 and 71- 72 are rejected under 35 U.S.C. 102(e) as being anticipated by US 20050037949A1.

The `949 publication teaches and claims a method of treating or preventing a disease in a subject comprising administering a pharmaceutical composition comprising isolated mannose binding lectin (MBL) (the MBL is human MBL, 92¶) together with a pharmaceutically acceptable carrier or diluent, wherein the subject is a bone marrow allograft recipient (see published claims 19-20 and 29-30, in particular), wherein the subjects MBL levels are below 500 ng/ml, such as individuals having an MBL level below 250 ng/ml (see 123¶-129¶, in particular). Further, the `949 publication teaches the use of a composition comprising isolated non-recombinant MBL in the manufacture of a medicament for use in administering to a subject in need of said composition (see 46¶ in particular). Examples of suitable recipients include, but are not limited to, bone marrow allograft recipients. Typically, the subject has an MBL deficiency (see 47¶ in particular). The `949 publication also teaches that the effect of MBL structural gene mutations and low levels of circulating MBL has been clearly associated with increased incidence of infection and severity of infection (see 16¶ in particular).

The `949 publication teaches that the structural unit of MBL is a 96 kDa collagen triple helix of three 32 kDa subunits (monomer). MBL oligomerizes as multiples of this 96 kDa unit and the native protein is commonly found as trimers to hexamers ranging from 270 kDa to approximately 650 kDa (see 3¶).

The `949 publication teaches that compositions of the present invention may be co-administered with compositions comprising unactivated purified MASPs (see 97¶ in particular).

The `949 publication teaches that in patients in whom the adaptive immune response has been compromised by chemotherapeutic regimens, the effect of MBL structural gene mutations and low levels of circulating MBL has been clearly associated with increased incidence of infection and severity of infection. Adults receiving chemotherapy for haematological malignancies with MBL levels below 0.5 μg/ml (500 ng/ml) had significantly increased incidence and severity of infection. Donor and recipient MBL genotype were found to be important in influencing the risk of infection in adults following allogeneic stem cell transplantation. Amongst 100 children undergoing chemotherapy, those with structural MBL gene mutations had twice as many days of febrile neutropenia as those with wild type MBL genes and four of these were admitted to ICU (critically ill) with infection. MBL levels less than 1μg/ml (1000 ng/ml) were thought to be critical in this study (see 16¶ in particular).

The reference teachings anticipate the claimed invention.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 51 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050037949A1 in view of US. Pat. No. 6,245,334.

The teachings of `949 publication have been discussed, supra.

The claimed invention differs from the reference teachings only by the recitation the administration of MBL to the individual prior to another treatment at ICUs in claim 68, simultaneously, sequentially or separately with another treatment in claim 69, prior to during or after said other treatment in claim 70.

The `334 patent teaches that since these lectin proteins are immune system regulators, they are also useful in the prevention of graft-versus-host disease and inhibition of rejection of transplants in general. Thus, the inventive lectins and fragments can be administered in conjunction with various surgical transplantations including skin allografts, bone marrow transplants, and organ transplants such as kidney, heart, liver or lung transplants. When used as an immunosuppressant, either in treating autoimmune conditions or in preventing transplant rejection, the lectins and fragments of the present invention can be administered along with amounts of known general immunosuppressants that enhance their effects. Such suitable general immunosuppressants include, for example, cyclophosphamide, prednisone, cyclosporin, rapamycin, other macrolide derivatives such as FK506, azathioprine, mycophenolic acid, anti-Tac, lymphocyte immune globulin, and OKT3 antibodies. The inventive lectins and fragments thereof can be administered simultaneously or sequentially with general immunosuppressants.

The determination of the optimal intervals of treatment is well within the purview of one of ordinary skill in the art at the time the invention was made and lends no patentable import to the claimed invention (the duration of treatment , the specific rout of administration and like factors within the knowledge and expertise of the medical practitioner) . Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or

workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to co-administer MBL along with amounts of known general immunosuppressants as taught by the '334 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhance immunosuppressants effects.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claims 51-52 and 54-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullighan et al (Blood 99(10):3524-3529, May2002).

Mullighan *et al* teach that MBL gene polymorphisms are associated with major infection following allogeneic hemopoietic stem cell transplantation (SCT). Mullighan et al teach that MBL2 genotype influences the risk of infection following allogeneic SCT and that both donor and recipient MBL2 genotype are important. Mulligan et al also teach that these findings raise the possibility that MBL replacement therapy may be useful following transplantation (see abstract). Mullighan et al teach that there is considerable interest in the role of purified or recombinant MBL as a potential therapeutic agent. Early data suggest that administration of purified MBL is safe and may be effective in ameliorating infection frequency in MBL-deficient individuals. Intensive antimicrobial treatment for infection after SCT is often toxic or unsuccessful, and existing strategies to prevent infection such as prophylactic antimicrobials and intravenous immunoglobulin (which contains non MBL) are incompletely effective. Further, if MBL deficiency is confirmed by future genetic and functional studies to be a major risk factor for infection after SCT, this clinical setting would be an ideal scenario for a clinical trial of MBL replacement therapy (see page 3529 last ¶ in particular). In addition, Mullighan et al teach that life-threatening complications such as GVHD and infection remain major barriers to the success of allogenenic hemopoietic SCT. While pretransplantation conditioning and posttransplantation immunosuppression are important risk factors for infection, the reasons that similarly immunosuppressed transplant recipients show maked variation in frequency of infection after allogeneic SCT are unclear. MBL deficiency is a risk factor for infection in other situations where immunity is compromised (see abstract).

Mullighan's *et al* teaching differs from the claimed invention by not expressly exemplifying MBL replacement therapy *in vivo* and the combination therapy.

However, it would be conventional and within the skill of the art to easily adapt the mullighan's et al teachings to an in vivo model of SCT. It would be obvious to combine the MBL replacement therapy with the immunosuppression drugs. It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. It would be conventional-and within the preview of those skilled in the art to identify and determine the optimum treatment protocols to treat SCT. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 8, 2007

Maher Haddad

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